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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/796,787	03/08/2004	Jeffrey H. Burbank	53951-122	1673

21890 7590 11/16/2005

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EXAMINER

BIANCO, PATRICIA

ART UNIT PAPER NUMBER

3761

DATE MAILED: 11/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

SP

Office Action Summary	Application No. 10/796,787	Applicant(s) BURBANK ET AL.	
	Examiner Patricia M. Bianco	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>8/06/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

In the Preliminary Amendments, Applicant has indicated co-pending applications in the first paragraph of the specification. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No. _____" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

Information Disclosure Statement

The information disclosure statement filed 08/06/04 cited an article or summary by Collins et al. cited "Clinical Comparison of Hemodialysis and Hemofiltration" from Dec. 1985. No copy this non-patent literature publication or that portion which caused it to be listed was supplied. It has not been considered at this time.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 7-12, 14, & 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Lichtenstein (4,370,983). Lichtenstein discloses a medical system and method of use for blood processing or treatment. The system has tubing forming a fluid circuit for blood, waste fluids, and infusion fluids. The tubing, a pump, valves and multiple sensors are along the length of tubing and all are enclosed in a module (i.e. cassette) made of flexible sheets to form a circuit. The system and its operation are under the control of a computerized system that may be connected to a central monitoring station via a network. The medical system can perform hemofiltration treatment, which is seen to be equivalent to renal replacement therapy and will therefore include a filter. The system's controller includes a computer or microcomputer that can be preprogrammed with multiple programs for carrying out many different procedures. The controller monitors various parameters of the hemofiltration therapy procedure, receives signals from various sensors monitoring said parameters, and can adjust the system components as necessary based on the parameters. Examples of parameters monitored are pressures, flow rates, and the like. Lichtenstein also teaches that a replacement fluid can be added to the blood return if a patient requires an increase in blood volume as a result of therapy based on fluid withdrawal monitoring.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 6 & 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lichtenstein ('983) in view of Manica (5,679,245). Lichtenstein substantially discloses the invention as claimed except for including a clamping region for occlusion of the flow tubing in response to a force externally applied thereto.

Manica discloses a blood treatment apparatus wherein the apparatus includes a filtration unit and a tubing assembly. Said apparatus may be used to perform hemofiltration procedures. The tubing assembly is formed as a module that includes region of tubing that is in communication with a clamp for occluding fluid flow through the tubing if there is a malfunction in the system. During a treatment procedure this clamping function is important because if the operator has to make changes to the procedure the apparatus will automatically clamp the tubing until the correction has been made.

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At the time of the invention, it would have been obvious to one having ordinary skill in the art to modify the fluid circuit of Lichtenstein by adding the clamping feature as taught by Manica to be able to occlude fluid flow through the tubing if there is a malfunction in the system. During a treatment procedure this clamping function is important because if the operator has to make changes to the procedure the apparatus will automatically clamp the tubing until the correction has been made.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-15 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. **6,589,482**.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the application claims are a broader recitation of the invention than that of the issued patent, including all of the same limitations. The claims of the application claim a renal replacement therapy system having a blood treatment device

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and method for performing renal replacement. The patent claims recite an hemofiltration apparatus having a hemofilter and method for hemofiltration. Since a broad interpretation of hemofilter and hemofiltration includes a blood treatment device and renal replacement therapy, if a patent was to grant on the pending claims of this application applicant would be granted an unlawful extension of protection beyond the years of the **6,589,482** patent.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia M. Bianco whose telephone number is (571) 272-4940. The examiner can normally be reached on Monday to Friday 9:00-6:30, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

November 10th, 2005


PATRICIA BIANCO
PRIMARY EXAMINER

Patricia M Bianco
Primary Examiner
Art Unit 3761